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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,728	06/14/2006	Alberto Osio Sancho	00327.70000US00	4669
23628 7590 06/22/2011 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
06/22/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/582,728

Applicant(s)

OSIO SANCHO, ALBERTO

Examiner

Jeffrey T. Palenik

Art Unit

1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 1-3,8-14,16,18-24 and 51-53
Claim(s) withdrawn from consideration: 4-7,15,17,25-27,39,41-46 and 50

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's entered amendments are sufficient in overcoming the indefiniteness rejection made to claim 12 under the second paragraph of 35 USC 112.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's remarks with regard to the rejection of claims 1-3, 8-14, 16, 18-24 and 51-53 under 35 USC 103(a) as being unpatentable over the combined teachings of Harris et al., Marmo et al. and Karageozian et al. have been fully considered but they are not persuasive.

As an initial matter, in response to Applicant's argument that the Examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Secondly, in response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Next, Applicant's Rule 132 Declaration filed with the response has been both entered and fully considered. However, the Examiner respectfully fails to see how it weighs against the merits of the rejection of record. That is, while it clearly discusses Applicant's product as a "game-changing breakthrough" and "non-invasive" treatment and certain merits it may have, it fails to show how the instantly claimed method is non-obvious over the art of record and more importantly, an improved "non-invasive" method. As such, the press-release provided is considered by the Examiner as unpersuasive.

Lastly, regarding the rejection, Applicant alleges that the claims, as amended, are sufficient in overcoming the art of record. It also appears that there is further confusion on the record concerning teachings of combinations of hyaluronidase and collagenase in the eye-drop formulations.

In response, the Examiner respectfully disagrees with Applicant's position and maintains the rejection. Addressing the second remark first, the Examiner notes that the teachings of Harris do, in fact, expressly disclose eye-drop formulations which contain both hyaluronidase [0013]-[0014] and collagenase compounds [0022]. Collagenases, by definition are enzymes which break down collagen. This is well-known in the art and is acknowledged by Applicant in the instant disclosure. Further, Applicant's instant disclosure defines collagenases as including such compounds as metalloproteinase-1, for example. This compound is clearly disclosed in [0022] of Harris as an additional corneal softening agent which may also be delivered in eye-drop form. Thus, the combination of both hyaluronidase and collagenase in eye-drop form is clearly taught and suggested by the reference, alone or in combination with the remaining references.

Applicant's remarks directed to the amendments claiming a "non-invasive" method are unpersuasive in light of the art as well as his own admission on the record. Specifically, Harris, for example, is directed to the application of a contact lens in combination with an eye-drop formulation which arguably contains both hyaluronidase and collagenase for the purposes of treating (e.g., reducing or eliminating) refractive errors in the eyes [0001]. Applicant's amendment is defining the non-invasive method as the application of a contact lens and eye-drops as taught in the art. Applicant, in support of his amendments states that "[i]t is generally understood from the present Application that 'non-invasive' excludes methods which require surgery". The Examiner agrees with this statement and maintains, for example, that Harris does not require surgery. Rather, [0121] discusses surgical corrections as reasons for employing the methods of Harris as opposed to methods for carrying out the correction. Applicant further discusses that the Harris reference directs the ordinarily skilled artisan to inject the formulation directly into the eye. However, the Examiner maintains the lens/eye-drop method is the preferred method which is taught as the reference expressly acknowledges that such injections would be unpleasant to a subject [0061]. As such, it is the continued position of the Examiner that the ordinarily skilled artisan would have been motivated to devise and arrive at the instantly claimed method, absent a clear showing of evidence to the contrary.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore maintained.